

**Notice of Allowability**

Application No.

09/297,040

Examiner

Samuel W. Liu

Applicant(s)

MOSE LARSEN ET AL.

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/18/05.
2. ☒ The allowed claim(s) is/are 28,29 and 32.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>12-21-05</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment  |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                         |
|   | 9. <input type="checkbox"/> Other _____.   |

### **DETAILED ACTION**

The amendment filed 11/18/05, which amends claims 28 and cancels claim 33 have been entered. The pending claims 1-32 and 34-39 are examined in this Office action.

### **EXAMINER'S AMENDMENT**

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Timothy J. Shea, Jr., on December 21, 2005. Applicants agree to the examiner proposed amendment to 1-32 and 34-39 (see below).

#### **Amendments to the claim:**

The pending claims 1-32 and 34-39 have been amended/deleted as follows. Please replace the previous claims with the claims shown below.

Cancel 1-27.

Claim 28 (*Amended*): The method for ameliorating the symptoms of diabetes in a subject having the diabetes, ~~said method~~ comprising administering to said subject a therapeutically effective amount of a protein comprising ~~an amino acid sequence having at least 90% sequence identity to~~ human galectin-3 of (SEQ ID NO:4), wherein said protein is a protective diabetes mediating protein that ameliorates symptoms of diabetes in said subject.

Cancel claims 30-31 and 34-39.

#### **Amendment to the specification:**

Insert the following paragraph before the "Description" paragraph:

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This application is a 371 of PCT/IB9701627 filed 10/24/1997, which claims the benefit under 35 USC 119(e) of earlier filed provisional applications: 60029324 filed 10/25/1996, 60030186 filed 11/05/1996, and 60030088 filed 11/05/1996.

On page 7, line 21, change "human galectin" to "human galectin-3".

On page 17, line 18, change "human galectin (SEQ ID NO:4)" to "human galectin-3 (SEQ ID NO:4)".

**Objection to the specification and drawings:**

On page 53, line 3 sets forth "NEPHGE 298" is "galectin-3" protein whereas line 8 indicates "NEPHGE 298" is "unknown" protein having molecular weight: 36,400 and pI value: 8.32. Clarification of this ambiguity is required.

The drawings filed 4/26/1999 are objected to because Figures 2-5 lack the corresponding sequence identifiers, i.e., SEQ ID NOs:\_ which are provided in the "Sequence Listing" filed 12/10/01.

*Conclusion:* claims 28-29 and 32 are allowed.

The following is an **Examiner's Statement of Reasons for Allowance:**

The rejection under 35 USC 112, first paragraph in the office action mailed 5/18/05 is withdrawn in light of that the amendment set forth above, and that prior art does not fairly teach or suggest the method of ameliorating diabetes comprising administering to the subject suffering from said diabetes the polypeptide (galectin-3) of SEQ ID NO:4. Thus, claims 28-29 and 32 are allowed.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

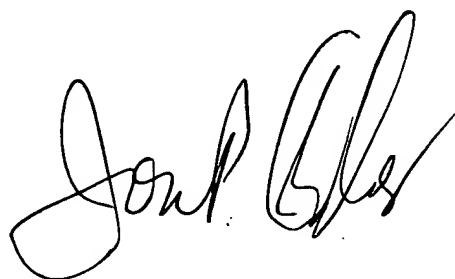
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached from 9:30 A.M. to 6:00 P.M. If attempts to reach

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the Examiner by telephone are unsuccessful, the Examiner's supervisor, Jon Weber, can be reached at (571) 272-0925. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.



Samuel W. Liu, Ph.D.  
Art Unit 1653, Examiner  
December 22, 2005



JON WEBER  
SUPERVISORY PATENT EXAMINER